REMARKS/ARGUMENTS

Claims 1-5 and 7-21 are pending

Claims 1 and 20-21 are supported in paragraph [0010] of the originally filed application.

No new matter is added.

The Action rejects the claims in view of the previously cited Koike reference and newly cited US 5,466,464 to Masaki. The Examiner acknowledges that Koiki does not describe the ratio of mannitol to other saccharides and thus relies on the Masaki patent to fill in the deficiency. Specifically, the Examiner finds that Masaki describes a Tablet preparation that includes different blending ratios of mannitol to, for example, lactose in Table 6 (see column 12) which have different disintegration values as shown in Table 1 (see column 9). Therefore, the Examiner argues that it would have been obvious to optimize the ratio of these components to achieve the desired effect, i.e., disintegration time.

Applicants respectfully disagree. First and of significance is Masaki's statement that "A structural body having desired hardness and disintegration rate (dissolution rate) can be obtained **regardless** of their mixing ratio." See col. 3, lines 43-45. This discussion would have clearly indicated to one skilled in the art that the ratios are not important and certainly have no basis to modify the ratios to achieve any effect given Masaki's clear teachings that those ratios are of little importance. Further, many of the blending ratios identified in Table 6 of Masaki fall outside of the scope of the claims and provide nothing with respect to having an excellent balance of both improved oral disintegration times and tabletting properties as shown by the evidence presented in this case.

Assuming that sufficient motivation and guidance is considered to have been provided by the cited references to arrive at the claimed weight ratio of mannitol to other saccharide(s) of (98-

75) : (2-25), which is clearly not the case, such is rebutted by a showing of superior properties as discussed at length in the previous response.

Briefly and again, as discussed in the present specification and shown by the comparative experimental data presented in the present specification and Table A of the attached 37 C.F.R. § 1.132 Declaration submitted, Applicants have discovered that the tablet compositions of Examples B, 9 and C, which comprise mannitol and other saccharide(s) in the claimed weight ratio of (98-75) : (2-25) in accordance with an exemplary aspect of the present invention, exhibit superior properties with respect to an excellent balance of both improved oral disintegration times and tabletting properties, as compared to the inferior properties exhibited by the tablet compositions of Comparative Examples A and D, which comprise mannitol and other saccharide(s) outside the claimed weight ratio of (98-75) : (2-25) (See e.g., page 3, lines 20-25, page 4, lines 1-6, page 6, lines 4-9, page 9, lines 17-21, page 10, lines 3-6, page 30, Example 9).

The comparative experimental data presented in the Declaration's Table A demonstrates that superior properties with respect to an excellent balance of both improved oral disintegration times and tabletting properties are exhibited by a composition having a weight ratio of mannitol to other saccharide(s) of (98-75) : (2-25) in accordance with the present invention, as compared to the inferior properties exhibited by a conventional composition having a weight ratio of mannitol to other saccharide(s) outside (98-75) : (2-25).

The hardness value for each of the Tablets is 3.5 kg and the tabletting pressure was varied for each tablet to achieve a consistent hardness value for each tablet. Generally, the disintegration time is measured for tablets having the same hardness because it is well known in the field that varying tablet hardness effects the disintegration time and so as to insure that the effects observed were a result of the composition and not the hardness.

This evidence clearly demonstrates that the tablet compositions of Examples B, 9 and C, which contain mannitol and other saccharide(s) in the weight ratio of (98-75) : (2-25) in accordance

with the present invention, exhibit superior properties with respect to an excellent balance of both improved oral disintegration times and tabletting properties, as compared to the inferior tabletting property exhibited by the tablet composition of Comparative Example A, which has a weight ratio of mannitol and other saccharide(s) of (100) : (0), and the inferior oral disintegration time property exhibited by the tablet composition of Comparative Example D, which has a weight ratio of mannitol and other saccharide(s) of (65) : (3), which is similar to the weight ratio described in Koike.

Examples similar in composition to Examples B, 9 and C above, but containing, in place of lactose, other saccharide(s) selected from sorbitol, erythritol, maltitol, sucrose, glucose, fructose, maltose, trehalose, paratinit and paratinose, would exhibit comparable properties to those of Examples B, 9 and C above with respect to an excellent balance of both improved oral disintegration times and tabletting properties (See e.g., the Table at page 30 of the present specification). I am aware of no reason to believe otherwise. More specifically, the tablets should have (1) superior oral disintegration time, (2) appropriate tablet hardness, (3) tabletting pressure, and (4) useful tablets at the end.

If the tablets do not have an appropriate hardness (typically about 3 kg or above), the tablets are friable making it difficult to manufacture, store and transport the tablet. However, if the tableting pressure is too high, too high a load is placed on the apparatus used for manufacture causing deleterious effects on the machine. Further, when placing such a high load on the tablets, the resultant tablets are typically broken, chipped or cracked and have little commercial value.

The Examiner has stated "given the disintegration time of the claimed range falls within the comparative examples A and D" which he has explained to mean that the two comparative examples demonstrate weight ratios of mannitol to lactose above and below the claimed range, each resulting in a oral disintegration time above and below the inventive examples B, 9 and C. Accordingly, the Examiner concludes that optimizing the ratio between comparative Examples A

and D would have yielded an expectation for the oral disintegration times demonstrated for inventive examples B, 9 and C. However, the present application demonstrates that the ratio of mannitol and lactose as claimed in claim 1 yields an improved tablet having an excellent balance (1) superior oral disintegration time, (2) appropriate tablet hardness, (3) tabletting pressure, and (4) useful tablets at the end.

In summary, Comparative Example D did not result in a tablet with sufficient oral disintegration time and Comparative Example A, while having satisfactory disintegration, produced tablets have the negative effects of sticking and binding, meaning that the tablets are unsuitable for commercial use. Therefore, while each of Comparative Examples A and D had different problems, the ratio of mannitol and lactose defined in Claim 1 solved these problems giving the excellent balance of properties required for a suitable final tablet.

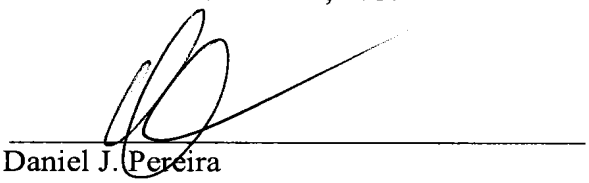
Withdrawal of these grounds of rejection is respectfully requested.

To the provisional obviousness-type double patenting rejections of claims 1-13 and 16-19 over claims 1, 3-28 and 30-32 of copending application 10/945,049 (Tanaka '240, U.S. 2005/0106240, in accordance with MPEP 822.01, it may be appropriate if the "provisional" double patenting rejection is the only rejection remaining, the examiner can withdraw the rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application into a double patenting rejection at the time the present application issues as a patent.

Applicants submit that the present application is now in condition for allowance and notification to this effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Daniel J. Pereira
Attorney of Record
Registration No. 45,518

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 06/04)